4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-N-2016-1493]

Erythropoietic Protoporphyria; Scientific Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public workshop and an opportunity for public comment on Erythropoietic Protoporphyria (EPP). The public workshop is intended to discuss how best to facilitate and expedite the development of safe and effective drug therapies to treat signs and symptoms related to EPP. FDA will provide information for, and gain perspective from, patients and patient advocacy organizations, health care providers, academic experts, and industry on disease symptoms and its impact on daily life, experience with current treatment regimens for EPP, and various aspects of clinical development of products intended to treat EPP. The input from this public workshop will help in developing topics for further discussion.

DATES: The public workshop will be held on October 24, 2016, from 10 a.m. to 4 p.m. Submit electronic or written comments to the public docket by December 24, 2016. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Participants must enter through Bldg. 1 and undergo security screening. For more information on parking and security procedures, please refer to

http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-N-2016-1493. Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FDA will post the agenda approximately 5 days before the workshop at: http://www.fda.gov/Drugs/NewsEvents/ucm501389.htm.

FOR FURTHER INFORMATION CONTACT: Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1146, Silver Spring, MD 20993-0002, 240-402-6525, FAX: 301-847-8443, Meghana.Chalasani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Public Workshop Information

A. Purpose and Scope of the Workshop

FDA is announcing a public workshop and an opportunity for public comment on Erythropoietic Protoporphyria (EPP). EPP is a group of genetic disorders that is characterized by photosensitivity that often manifests as severe pain, swelling and/or burning. Treatment for EPP focuses on minimizing sun exposure. Other treatments may include dietary management, over-the-counter and prescription sunscreen, and phototherapy. The purpose of the workshop is to discuss issues that may affect the development of products for the treatments of EPP, and to provide a scientific and technical forum to consider issues related to clinical trial designs (including eligible populations and trial feasibility) and clinical trial endpoints. FDA will

provide information on current review considerations for new products in the United States, and gain perspective from patients and patient advocacy organizations, health care providers, academic experts, and industry on the most significant disease symptoms and its impact on daily life and experience with current treatment regimens for EPP. The input from this public workshop will help in developing topics for further discussion.

B. Workshop Attendance and Participation

Registration: If you wish to attend this workshop, visit https://eppscientificworkshop.eventbrite.com. Please register by October 17, 2016. If you are unable to attend the workshop in person, you can register to view a live Webcast of the workshop. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the workshop will be based on space availability. If you need special accommodations because of a disability, please contact Meghana Chalasani (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the workshop.

FDA will hold an open public comment period to give the public an opportunity to comment. Registration for open public comment will occur at the registration desk on the day of the workshop on a first-come, first-served basis.

Docket Comments: Regardless of if you attend the public workshop, you can submit electronic or written responses for consideration to the public docket (see ADDRESSES) by December 24, 2016. Received comments may be seen in the Division of Dockets Management

between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Transcripts: As soon as a transcript is available, FDA will post it at http://www.fda.gov/Drugs/NewsEvents/ucm501389.htm.

Dated: June 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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